

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 February 2009 has been entered.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on 07 April 2003, the certified copy was received 23 April 2009.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application. It is noted that the intervening PCT application (WO 2004/092400) was published in French.

Claim Status

Claims 1, 3, 8-12, 14-16, 20-21 are active in the case. Claims 2, 4-7, 13, 17-19 have been cancelled by amendment. Claims 1, 3, 8-12, 14-16, 20-21 are under examination; no claims are withdrawn as drawn to a non-elected invention.

Claim Objections

Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The rejection of claim 3, with dependent claims 6-11, under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment to the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8-12, 14-16, 20-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for media for detecting and/or identifying *Salmonella* or *Staphylococcus* using the two enzyme with inhibitor system, specifically using esterases or “osidases”, it does not reasonably provide enablement for the detection of any bacterium present in a sample. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims read on the products and the methods related to a two enzyme/one inhibitor system, wherein one of the enzymes is not free in the sample, to detect any bacterium of interest. Thus, the claims read on the use of this method to detect bacteria which

have no enzymes in common with the bacteria taught by the instant disclosure, thus the recited inhibitors would not be effective and any media or method with the instant limitations would not detect the bacteria, thus would not be enabled. The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art. The instant specification is not enabling for claims drawn to the detection of any bacteria, which may or may not possess esterases or osidases that may or may not react with the instant inhibitors the same way or may not react with them at all.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, (1) the amount of experimentation is enormous because the sheer number of types of bacteria and variations of esterases and “osidases”; (2) the amount of guidance provided by the specification is not large since the examples are primarily using Salmonella, with one Staphylococcus example. Page 3 recites lists of genera that are envisioned, but does not provide any substantiation that the method will translate to all these types of bacteria or even that they all have the same esterases or respond to the inhibitors recited in the claims. One of skill in the art would have no idea what structural characteristics might make one inhibitor have activity in one type of bacteria and another type of bacteria may have altered or decreased activity or no activity at all. Continuing, (3) the specification lacks any working examples other than those disclosed above. As for the next Wands factor, (4) the nature of the invention is that media and methods of detecting Salmonella and Staphylococcus are taught wherein the media and methods rely on specific bacteria which react in a specific way to exemplified inhibitors. The prior art (5) shows that some inhibitor assays are known, but does not show that these assays translate to any bacteria; (6) the relative level of skill in this art is very high; (7) the predictability of the art is not high because the number of types of bacteria encompassed is large. Finally, (8) the claims are enormously broad. Based on this analysis, the conclusion that it would require undue experimentation to practice the instant invention is inescapable.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 3, 6-16 under 35 U.S.C. 103(a) is withdrawn in view of the amendments to the claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Hotelling - Generally, 9-6 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

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